

## Exhibit T

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ETHICON

cc: Mr. E. Block  
toINC.  
SOMERVILLE, NEW JERSEY  
June 15, 1982Dr. B. Schwartz  
Dr. E. Borysko  
Mr. P. K. Hopper  
Dr. R. Kronenthal  
toDr. A. J. Levy  
Mr. P. T. Makris  
Dr. J. McDivitt  
RDCF**To:** Dr. A. J. Melveger**Subject:** CRACK DEPTH IN EXPLANTED  
PROLENE\* POLYPROPYLENE SUTURES  
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A study was carried out of all available SEM photographs of explanted PROLENE sutures, to determine best estimates for the penetration depth of surface cracks. The micrographs were taken in 1981; the explants themselves are no longer available. SEM photographs examined were as follows:

<u>Photo #</u>	<u>Date</u>	<u>Source of PROLENE Explants</u>
5853-5874	7/27/81	ERF #81-266, sizes 4-0 and 5-0, cardio-vascular implants, 5 and 7½ years implantation time.
5627-5641	3/2/81	R. C. Drews, M.D. Size 10-0.
5767-5789	6/18/81	Ophthalmic implants, 2 months through 4½ years implantation time.

The 10-0 sutures showed surface cracks after 1-2 years implantation; the larger sutures after 7½ years but not at 5 (although cracks could be induced by abrasion on the 5 year explant, as previously reported by Dr. Borysko). Of those micrographs exhibiting surface cracks, three showed a clear, edge-on view of the cracked surface layer, permitting an accurate measurement of crack depth. Seven micrographs showed oblique views of cracks, from which only an estimate ( $\pm$  50%) of depth could be obtained. The data from all ten micrographs are shown in Table I.

The 10-0 sutures have crack depths of 0.5 to 2  $\mu$ m; the suture diameter is 25  $\mu$ m. Crack depth does not vary systematically with implantation time; it does vary significantly from point to point along the fiber length in both the 10-0 and the 4-0 sutures.



Anthony C. Lunn, Ph.D.

ETHICON, INC.

JUN 25 1982

RD-Central File

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Attachment

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TABLE I  
Crack Depth in PROLENE Explants

Explant Specimen	Suture Size	In vivo Time Yr	SEM Photo #	Magnif.	Crack depth $\mu\text{m}$
ERF #81-266 (cardiovascular)	4-0	7½	5872	2000 X	4.5*
			5873	2000 X	4 *
			5874 A/B	2000 X	2-4*
From Dr. R. C. Drews:					
A. Belikopitsky	10-0	2	5769	1000 X	1-1.5 <sup>+</sup>
E. Lucksinger	10-0	3	5783	~1700 X	1 <sup>+</sup>
A. Karchmer	10-0	3½	5780	1000 X	1.5 <sup>+</sup>
			5781	1000 X	2 <sup>+</sup>
Baum	10-0	4½	5633	2000 X	0.5-0.8 <sup>+</sup>
			5637	2000 X	0.5-0.8 <sup>+</sup>
			5641	1000 X	2 <sup>+</sup>

\* Edge-on view of cracks

+ Oblique view of cracks